JUL 2 2012

510(k) SUMMARY K113435

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237	
Date Summary Prepared:	June 25, 2012	
Device:	Trade Name:	ACE Axcel Clinical Chemistry System
	Classification:	Class 1
	Common/Classification Name:	Analyzer, Chemistry (Photometric, Discrete), For Clinical Use (21 C. F.R. § 862.2610) Product Code JJE
	Trade Name:	ACE Carbon Dioxide (CO_2-LC) Reagent
	Classification:	Class 2
	Common/Classification Name:	Enzymatic, Carbon-Dioxide (21 C. F.R. § 862.1160) Product Code KHS
	Trade Name:	ACE Direct Bilirubin Reagent
	Classification:	Class 2
	Common/Classification Name:	Diazo Colorimetry, Bilirubin (21 C. F.R. § 862.1110) Product Code CIG
	Trade Name:	ACE Total Bilirubin Reagent
	Classification:	Class 2
	Common/Classification Name:	Diazo Colorimetry, Bilirubin (21 C. F.R. § 862.1110) Product Code CIG

	Trade Name:	ACE Magnesium Reagent
	Classification:	Class 1
	Common/Classification Name:	Photometric Method, Magnesium (21 C. F.R. § 862.1495) Product Code JGJ
Predicate Devices:	Manufacturer for analyzer/reagent system predicate: Alfa Wassermann ACE Clinical Chemistry System ACE Reagents (K931786)	
Device Descriptions:	The ACE Axcel Clinical Chemistry System consists of two major components, the chemistry instrument and an integrated Panel PC. The instrument accepts the physical patient samples, performs the appropriate optical or potentiometric measurements on those samples and communicates that data to an integral Panel PC. The Panel PC uses keyboard or touch screen input to manually enter a variety of data, control and accept data from the instrument, manage and maintain system information and generate reports relative to patient status and instrument performance. The Panel PC also allows remote download of patient requisitions and upload of patient results via a standard interface. In the ACE Carbon Dioxide (CO_2-LC) Reagent assay, serum carbon dioxide (in the form of bicarbonate) reacts with phosphoenolpyruvate in the presence of phosphoenolpyruvate carboxylase and magnesium to yield oxaloacetic acid and phosphate. In the presence of malate dehydrogenase, the reduced cofactor is oxidized by oxaloacetic acid. The reduced cofactor absorbs strongly at 408 nm whereas its oxidized form does not. The rate of decrease in absorbance, monitored bichromatically at 408 nm/692 nm, is proportional to the carbon dioxide content of the sample. In the ACE Direct Bilirubin Reagent assay, sodium nitrite added to sulfanilic acid forms diazotized sulfanilic acid. Bilirubin glucuronide in serum reacts with diazotized sulfanilic acid to form azobilirubin, which absorbs strongly at 554 nm. The increase in absorbance, measured bichromatically at 554 nm/692 nm, one minute after sample addition, is directly proportional to the direct bilirubin concentration. In the ACE Total Bilirubin Reagent assay, sodium nitrite, when added to sulfanilic acid, forms diazotized sulfanilic acid. Bilirubin in serum reacts with diazotized sulfanilic acid to form azobilirubin, which absorbs strongly at 554 nm. The inclusion of dimethyl sulfoxide (DMSO) in the reagent as an accelerator causes both direct and indirect bilirubin to react rapidly. The increase in absorbance, measured bichromatically at 554 nm/692 nm, is directly proportional to the total bilirubin concentration in the sample. Magnesium ions in serum react with Xylidyl blue-1 in an alkaline medium to produce a red complex which is measured bichromatically at 525 nm/692 nm. The intensity of color produced is directly proportional to the magnesium concentration in the sample. EGTA prevents calcium interference by preferential chelation of calcium present in the sample. A surfactant system is included to remove protein interference.	

Intended Use:	Indications for Use: The ACE Axcel Clinical Chemistry System is an automated, discrete, bench-top, random access analyzer that is intended for *in vitro* diagnostic use in the quantitative determination of constituents in blood and other fluids. The ACE Carbon Dioxide (CO_2-LC) Reagent is intended for the quantitative determination of carbon dioxide concentration in serum using the ACE Axcel Clinical Chemistry System. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only. The ACE Direct Bilirubin Reagent is intended for the quantitative determination of direct bilirubin concentration in serum using the ACE Axcel Clinical Chemistry System. Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic, hematological and metabolic disorders, including hepatitis and gall bladder block. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only. The ACE Total Bilirubin Reagent is intended for the quantitative determination of total bilirubin concentration in serum using the ACE Axcel Clinical Chemistry System. Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic, hematological and metabolic disorders, including hepatitis and gall bladder block. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only. The ACE Magnesium Reagent is intended for the quantitative determination of magnesium concentration in serum using the ACE Axcel Clinical Chemistry System. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low serum levels of magnesium) and hypermagnesemia (abnormally high serum levels of magnesium). This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

Technological Characteristics:	The following is a description of the major features of the ACE Axcel Clinical Chemistry System: • System throughput is approximately 160 test results per hour for routine, single reagent chemistries. System throughput will be higher when the test workload includes ISE's. • The instrument has a capacity of 40 reagent containers on board. A reagent cooling system maintains the reagents at 12°C during instrument operation. • Reagent containers are identified by computer coded labels to simplify system operation. All reagents in the system must include an identification label on the container. • Sample and reagent sensing notify the operator of a depleted condition during operation. • The system performs analysis at a reaction temperature of 37°C. • An electrolyte subsystem capable of measuring sodium, potassium and chloride concentrations is included. • Primary draw tubes may be introduced one at a time into the system for closed tube sampling. Positive tube identification can be achieved with an optional barcode scanner. An aliquot volume sufficient for all tests ordered is transferred and stored and the closed tube is returned to the user. • Sample cups are introduced to the system one at a time or by sample ring segment. • Disposable cuvettes are loaded in bulk and then automatically injected as needed by a cuvette hopper system. The ACE Axcel clinical chemistry optical system is capable of monitoring a maximum of 48 cuvettes at one time. • The absorbance optical system is capable of absorbance measurements in a linear range of 0.0 to 2.0 absorbance units (at 0.67 cm pathlength). Sixteen wavelengths are measured simultaneously using a photodiode array. The ACE Carbon Dioxide (CO_2-LC) Reagent consists of a single reagent bottle. The reagent contains Phosphoenolpyruvate, nicotinamide adenine dinucleotide, analog, reduced, phosphoenol pyruvate carboxylase and malate dehydrogenase. The ACE Direct Bilirubin Reagent is composed of two reagent bottles (Direct Bilirubin Reagent and Sodium Nitrite Reagent). The reagents contain sulfanilic Acid, hydrochloric acid, and sodium nitrite. The ACE Total Bilirubin Reagent is composed of two reagent bottles (Total Bilirubin Reagent and Sodium Nitrite Reagent). The reagents contain sulfanilic acid, hydrochloric Acid, DMSO and sodium Nitrite. The ACE Magnesium Reagent is composed of a single reagent bottle. The reagent contains Xylidyl blue-1 and EGTA.

Performance Data:	Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE Axcel Clinical Chemistry System included precision, accuracy, and detection limit data. ACE Carbon Dioxide (CO_2-LC) Reagent Precision: In testing conducted at four CO_2 levels for 22 days, the within-run CV ranged from 1.6 to 8.7%, and total CV ranged from 4.3 to 12.2%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 1.0 to 2.6% and total CV ranged from 1.8 to 5.7%. Accuracy: In the correlation study, 120 samples with CO_2 values ranging from 3.2 to 47.6 mEq/L were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9758, a standard error estimate of 1.31, a confidence interval slope of 0.946 to 1.025, and a confidence interval intercept of -1.15 to 0.73. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9819 to 0.9952, standard error estimates of 0.80 to 1.21, confidence interval slopes of 0.951 to 1.081, and a confidence interval intercepts of -1.99 to 1.65. Detection limit: The detection limit was 1.2 mEq/L. ACE Direct Bilirubin Reagent Precision: In testing conducted at four direct bilirubin levels for 22 days, the within-run CV ranged from 0.8 to 16.5%, and total CV ranged from 1.5 to 16.6%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.0 to 4.6% and total CV ranged from 0.0 to 4.6%. Accuracy: In the correlation study, 116 samples with direct bilirubin values ranging from 0.2 to 12.5 mg/dL were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9996, a standard error estimate of 0.05, a confidence interval slope of 0.967 to 0.978, and a confidence interval intercept of -0.01 to 0.01. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9996 to 0.9997, standard error estimates of 0.07 to 0.09, confidence interval slopes of 0.984 to 1.025, and a confidence interval intercepts of -0.03 to 0.03. Detection limit: The detection limit was 0.1 mg/dL.

	ACE Total Bilirubin Reagent Precision: In testing conducted at four total bilirubin levels for 22 days, the within-run CV ranged from 0.6 to 10.6%, and total CV ranged from 1.1 to 10.6%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.9 to 22.1% and total CV ranged from 0.0 to 3.3%. Accuracy: In the correlation study, 117 samples with total bilirubin values ranging from 0.2 to 34.8 mg/dL were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9997, a standard error estimate of 0.13, a confidence interval slope of 0.961 to 0.970, and a confidence interval intercept of -0.02 to 0.03. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9993 to 1.0000, standard error estimates of 0.08 to 0.25, confidence interval slopes of 1.012 to 1.056, and a confidence interval intercepts of -0.12 to 0.05. Detection limit: The detection limit was 0.2 mg/dL. ACE Magnesium Reagent Precision: In testing conducted at four magnesium levels for 22 days, the within-run CV ranged from 2.7 to 5.9%, and total CV ranged from 4.1 to 7.6%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 1.2 to 4.1% and total CV ranged from 2.0 to 6.9%. Accuracy: In the correlation study, 108 samples with magnesium values ranging from 0.6 to 5.5 mg/dL were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9690, a standard error estimate of 0.14, a confidence interval slope of 0.950 to 1.046, and a confidence interval intercept of -0.07 to 0.12. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9858 to 0.9930, standard error estimates of 0.11 to 0.18, confidence interval slopes of 0.920 to 1.089, and a confidence interval intercepts of -0.39 to 0.22. Detection limit: The detection limit was 0.2 mg/dL.
Conclusions:	Based on the foregoing data, the device is safe and effective. These data also indicate substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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West Caldwell, NJ 07006

JUL 2 2012

Re: k113435
Trade Name: ACE Carbon Dioxide (CO_2-LC) Reagent
ACE Direct Bilirubin Reagent
ACE Total Bilirubin Reagent
ACE Magnesium Reagent
Regulation Number: 21 CFR §862.1160
Regulation Name: Bicarbonate/Carbon-Dioxide test system
Regulatory Class: Class II
Product Codes: KHS, CIG, JGJ
Dated: May 11, 2012
Received: May 14, 2012

Dear Dr Katz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113435

Device Name: ACE Carbon Dioxide (CO_2-LC) Reagent

Indications for Use: The ACE Carbon Dioxide (CO_2-LC) Reagent is intended for the quantitative determination of carbon dioxide concentration in serum using the ACE Axcel Clinical Chemistry System. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

Device Name: ACE Direct Bilirubin Reagent

Indications for Use: The ACE Direct Bilirubin Reagent is intended for the quantitative determination of direct bilirubin concentration in serum using the ACE Axcel Clinical Chemistry System. Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic, hematological and metabolic disorders, including hepatitis and gall bladder block. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

Prescription Use X (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use. (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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Indications for Use

510(k) Number (if known): K113435

Device Name: ACE Total Bilirubin Reagent

Indications for Use: The ACE Total Bilirubin Reagent is intended for the quantitative determination of total bilirubin concentration in serum using the ACE Axcel Clinical Chemistry System. Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic, hematological and metabolic disorders, including hepatitis and gall bladder block. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

Device Name: ACE Magnesium Reagent

Indications for Use: The ACE Magnesium Reagent is intended for the quantitative determination of magnesium concentration in serum using the ACE Axcel Clinical Chemistry System. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low serum levels of magnesium) and hypermagnesemia (abnormally high serum levels of magnesium). This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

Prescription Use X (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use. (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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